Summary of Safety and Effectiveness

JAN 28 2011

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Trade Name:	NeuColonCARE
Version Number:	1.0
Common Name:	Soft-Copy Medical Image Reading Workstation
CFR Section:	21 CFR Part 892.2050
Classification Name:	Picture Archiving and Communication System (PACS).
Product Code:	LLZ
Device Class:	Class II
Applicable Standard:	DICOM 3.0
Manufacturer and Distributor:	Neusoft Medical Systems Co., Ltd. No.16,Shiji Road, Hunnan Industial Area, Shenyang,Liaoning, China Post Code : 110179
Submitter:	Contact : Tian Yuehui Title : Manager of Quality Management Department Tel : 86-24-83660646 Fax : 86-24-83780480 E-Mail :tianyh@neusoft.com Summary prepared : Nov.24,2010

Safety and Effectiveness Information

Intended Uses:

The NeuColonCARE is a soft-copy reading workstation intended for clinical review of CT abdominal (gastrointestinal) images which allows easy acquisition, transmission and review of the medical images and supports VC (Virtual Colonoscopy) function. Images may be interpreted by a trained physician to obtain information that may be useful in the determination of a diagnosis.

Device Description:

NeuColonCARE software product is a soft-copy reading workstation used to clinically evaluate the CT abdominal (gastrointestinal) images. It is a self-contained software package, providing the functions of patient information management, image viewer (2D view, standard MPR views and 3D visualization view), and the analysis and processing of the gastrointestinal system, especially the colon. It allows the user to conduct air segmentation based on a customized threshold value, extract the centerline automatically and interactively, view the colon lumen structure in the manner of virtual colonoscopy or virtual dissection along the centerline, view the ROI, and finally acquire useful clinical information by marking and measuring the ROI (3D distance and CT value).

Technological characteristics:

The NeuColonCARE software product is executed on a general PC and employs the same or similar fundamental technology as its predicate devices.

Summary of Non-Clinical Tests:

The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. A summary of the software design description, risk management, level of concern and verification&validation testing information can be found in the attached submission. It is further verified for system compatibility with the devices with which it communicates, including conformance to DICOM 3.0 standard.

Predicate Device:

K070831 : Voxar 3D Entreprise with ColonMetrix
K032096 : Philips ViewForum 2003

Statement of Substantial Equivalence:

The Neusoft NeuColonCARE is comparable and substantially equivalent to the Voxar 3D Entreprise with ColonMetrix (K070831) and the Philips ViewForum 2003 (K032096).

The NeuColonCARE and the Philips ViewForum 2003 share similar technological specifications. Both of them support DICOM protocol for communication of images with other medical imaging devices. Furthermore, they both provide various tools for physicians to view images.
The NeuColonCARE has the similar technological characteristics with the Voxar 3D Entreprise with ColonMetrix. Both of them provide functions such as standard MPR,Virtual Endoscopy, Virtual Dissection and they both provide the function of ROI bookmark and measurement, as well as quantitative analysis of the ROI.

According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

Conclusion:

The NeuColonCARE software product employs the same or similar fundamental technology as its predicate devices and dose not introduce any new potential safety risks. So, Neusoft Medical Systems considers the NeuColonCARE software product to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Neusoft Medical Systems Co., Ltd.
% Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Inc.
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JAN 28 2011

Re: K110077
Trade/Device Name: NeuColonCARE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 21, 2010
Received: January 11, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) : K110077

Device Name: NeuColonCARE

Indications for use:

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Prescription Use ____ √ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Deices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110077